

Attorney Docket No. 5697.200-US
Murray et al.
Serial No. 09/551,740 Filed April 18, 2000

RESPONSE

The examiner states in the Office Action Summary that claims numbered 1, 3, 4, 25-28, 31, 32, 38-42, and 51-54 are pending in the application; claims numbered 1, 3, 4, 25-28, 31, 32, 38-42, and 51-54 are rejected. Applicant respectfully directs the examiners attention to the amendment filed May 19, 2003, wherein claim number 3 was cancelled. Applicant respectfully submits claims numbered 1, 4, 25-28, 31-32, 38-42, and 51-54 are pending in the application.

(1) The examiner has rejected claims numbered 1, [3], 4, 25-28, 31-32, 38-42, and 51-54 under 35 U.S.C. §112, first paragraph, because the specification does not reasonably provide enablement for A1, A2 equal to saturated, unsaturated or aromatic 5-6 membered cyclic ring systems equal to thienyl and pyridinyl.

The examiner applies the first (breadth), second (nature of invention), fifth (level of predictability), sixth (amount of guidance) and eighth (quantity of experimentation) *Wands* (*In re Wands*, 858 F.2d 731 (Fed. Cir. 1988)) factors to support the assertion that the disclosure does not satisfy the enablement requirement.

In response to the first, sixth and eighth *Wands* factors, Applicant respectfully directs the examiner's attention to the specification as originally filed Example 11, page 39, line 22, Example 12, page 40, line 3, Example 29, page 47, line 1 and Example 30, page 47, line 16, all of which disclose synthetic schemes and characterization data for compounds having A1, A2 as pyridinyl. Additionally, Applicant respectfully directs the examiner's attention to the specification as originally filed Example 9, page 38, line 29, Example 10, page 40, line 9, Example 31, page 47, line 28 and Example 32, page 48, line 8, all of which disclose synthetic schemes and characterization data for compounds having A1, A2 as thienyl.

In response to the second, fifth, sixth and eighth *Wands* factors, Applicant respectfully submits one skilled in the relevant art would be able to apply the pharmacological methods described in the specification as filed beginning page 27, line 6 to test compounds of the present invention for pharmacological activity without undue experimentation. Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is "undue", not "experimentation." The determination of what constitutes undue experimentation in a case requires the application of a standard of reasonableness, having due

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regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).

Additionally, Applicant respectfully asserts test results on particular compounds are not a necessary component of enablement. Early filing of an application with its disclosure of novel compounds that possess significant therapeutic use is to be encouraged. Requiring specific testing of the thousands of analogs encompassed by the claims in order to satisfy the how-to-use requirement of 35 U.S.C. §112 would delay the disclosure and frustrate, rather than further, the interests of the public. *In re Bundy*, 642 F.2d 430 (C.C.P.A. 1981).


Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Applicant respectfully requests that, if the examiner does not believe the above places the claims in condition for allowance, the examiner provide an advisory action or contact the undersigned by telephone as soon as practicable.

The examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

Date: November 8, 2004


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